QI Meeting: Fri., January 18, 2008 11 – 12:30 Room: 133

Meeting Minutes

Attendees: Pat Jacobsen, Rozelta Boyd, Tracy Stiles, Kathleen Nawn, Jennifer Jenner, Linda Han, Cheryl Gauthier, Sandra Smole, Tanya Rivera, Mary Gilchrist, Xingtai Wang, Betsy Szymczak, Glenn Krumholz, Pete Kane, Karen Chen, Jill Clemmer, Kristen Pribeck, Arthur Kazianis, Julie Nassif, Annie Khan, Peter Piro, Paul Elvin, Chuck Salemi, Paul Servizio, Peter Belanger, Dina Caloggero, Peggy DiNatale

Items 1 and 2 will be discussed in more detail at a future meeting. QA distributed a copy of section 493.1239, General laboratory systems quality assessment of the CLIA regulations and the web address for the CLIA regulations.

1. **Develop criteria to assist differentiating issues that should be handled as problems from those handled as a corrective action**
   Laboratory Supervisors and Directors should have examples of issues identified during their record review during the months of November and December. We will discuss several different types of issues identified and begin to define some criteria to differentiate problems from corrective actions. If a Lab Supervisor wishes to use a handout, please ensure that all patient identifiers are removed.
2. **Laboratory Supervisors and Directors identify management reports** - Dina Caloggero
   Management reports that will assist you in monitoring areas critical to patient testing and turn around times or other areas of testing that are critical in your lab setting.

3. **Accuracy and precision of performing gravimetric pipette calibration for small volume (< 100 ul) pipettes**
   Jill Clemmer will present data obtained from gravimetric pipette calibration for small volume pipettes (< 100 ul). Please include the type of balance used for the calibration data that will be presented.

   Jill presented data for pipettes that were calibrated using a gravimetric method. The data included the following volumes: 10 uL, 20 uL, 100 ul and 200 ul. To demonstrate year to year precision, data from 2006 and 2007 was shown for the one of the pipettes. These measurements were taken using a Mettler Toldeo analytical balance, model XS205DU.

   At the conclusion of the discussion it was agreed that each Division would assess if they had at least one analytical balance that could provide measurement out to 4 decimal points. If a Division did not possess such a balance, the Division Director would contact another Division Director in order to work out the details of sharing the balance for pipette calibrations.

   The Biowatch program will be responsible for the Artel system for pipette calibration, this includes the SOP, instrument maintenance and ordering supplies. Biowatch will continue to use the Artel system. If other labs wish to use the Artel system, they should contact Glenn Krumholz to make arrangements.

4. **Review CLIA Regulations for Evaluation of PT testing** - Peggy DiNatale
   a. **CLIA Regulations**: A copy of the section 493.1236, Evaluation of proficiency testing performance, from the CLIA regulations was distributed and discussed.

   b. **Guidance document from CAP**: A copy of the guidance document that CAP includes in some of the PT survey result booklets was distributed. This document lists the exception codes that the CAP uses, a description of the codes and the suggested action to take for each exception code. Technical Supervisors and Division Directors should refer to this guidance document for PT surveys whenever the result for a specimen is not graded. This document can be used for PT surveys from other companies as well. It contains a quick list of action steps that can be taken and documented in order to comply with the CLIA regulations for evaluating PT performance.

c. **SLI's Self Evaluation form for ungraded PT surveys:** A copy of the revised Self Evaluation form was distributed. This document is now available on the F drive in the QA folder and is a form. This latest version has been streamlined from the previous version and is now a one page document. This form is generally initiated by the QA Department when the results of a PT survey are not graded. The routing of CAP survey results starts at QA. The routing of some PT survey results (LRN, NY State) begins with the Technical Supervisor, Manager or Division Director. In these cases, the survey can be sent o QA to start the self evaluation form or QA will send the electronic form to the Supervisor, Manager or Division Director to complete.

5. **Laboratory Audits** - Peggy DiNatale

   a. Review QA SOP, QA.010, <u>Laboratory Audits:</u>
   This SOP can be found on the F drive in the QA folder under SOPs.

   b. Distribute the 2008 schedule of Laboratory Audits:
   Four laboratory audits were conducted by QA between November, 2004 and November, 2006. The audit process and the audit reporting form were improved after each audit. The Laboratory Audit SOP was in a finalized and implemented as of September 4, 2007. Beginning in 2008, QA will conduct a laboratory audit of the CLIA regulated laboratories on a scheduled basis. A copy of the audit schedule was distributed. After we complete the audits for the CLIA regulated labs, QA can begin audits in the non-CLIA regulated laboratories.

6. **February Agenda items based on requests submitted by various Laboratory Supervisors and on questions posed to QA by several Lab Supervisors or Directors.**

   a. QA Study Project related to specimens sent out to the CDC

   b. Overview of and Differentiation between: Training / Competency Assessment / Annual Competency Assessment
   and
   How PT samples (CAP, CDC, LRN and in-house) can be used to satisfy requirements for both PT testing and assessment
   of personnel.

   c. Discussion of SOPs: Document control / SOP components / SOP Reviews